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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,480	12/10/1999	MARK CHEE	018547-03053	4017
33494	7590	06/22/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER 8TH FLOOR SAN FRANCISCO, CA 94111-3834			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/381,480	CHEE, MARK
<b>Examiner</b>	<b>Art Unit</b>	
	BJ Forman	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 04 April 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-15 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 April 2005 has been entered.

***Status of the Claims***

2. This action is in response to papers filed 4 April 2005 in which claims 1 and 15 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 December 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-15 are under prosecution.

***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. Provisional Application 60/041,435, filed 20 March 1997, upon which priority is claimed, does not provide adequate support under 35 U.S.C. 112 for claims 1-15 of this application. The amended claims are drawn to immobilized probes "spanning the known reference sequence". While the '435 application describes an array of "mapped markers" (page 4, lines 1-3), the application does not provide support for the newly claimed immobilized probes "spanning the

known reference sequence". Therefore, the effective filing date for the instant claims is the filing date of Provisional Application 60/073,853 i.e. 2 February 1998).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are indefinite in Claim 1, step (a) for the recitation "immobilized on at least one support" because it is unclear whether the recitation modifies the reference sequence or the probes.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 1-3, 5-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Gingeras et al (U.S. Patent No. 6,228,575, filed 7 February 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claims 1-15, Gingeras et al disclose the claimed method for analyzing a target sequence comprising the steps of designing an array of probes that span a known sequence and immobilizing the probes, hybridizing the target to the immobilized probes, determining relative hybridization to estimate the sequence, designing a second array from the estimated sequence and reestimating the sequence wherein the target is a variant of the reference, wherein the target is 50-90% identical to the reference wherein the probes comprise at least four probe sets complementary to and spanning the reference and wherein the reference encompasses up to 90% of the genome (Column 29, line 54-Column 32, line 52).

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-3, 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al (U.S. Patent No. 5,310,893, issued 10 May 1994) in view of Skiena (U.S. Patent No. 5,683,881, issued 4 November 1997).

Regarding Claims 1 & 15, Erlich discloses a method for analyzing a target sequence comprising the steps of designing an array of probes that span a known sequence and immobilizing the probes (Column 12, lines 25-40), hybridizing the target to the immobilized probes, determining relative hybridization to estimate the sequence and using DPalpha/DPbeta hybridization-identification followed by variant-specific hybridization-identification (Column 11, lines 28-46). Erlich further teaches the sequencing uses more than 14 sequence-specific hybridizations requiring multiple amplifications of the target (Example 10, Column 37, lines 25-28 and 57-60). Erlich do not teach designing a second array from the first hybridization to reestimate the sequence. However, second array design was well known in the art at the time the claimed invention was made as taught by Skiena.

Skiena teaches designing an array of probe complementary to an estimated sequence of the target wherein the array does not contain every possible probe of a given length (Claim 1, step d), hybridizing the array of probes to the target, determining a re-estimated sequence of the target from the hybridization and repeating the designing, hybridizing and determining (Column 4, lines 5-67 and Claim 2).

Skiena further teaches the interactive sequencing reduces the amount of synthesis, hybridization and analysis thereby reducing costs (Column 3, lines 45-48 and Column 4, lines 5-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the interactive sequencing of Skiena to the sequence analysis of Erlich which they specifically teach requires large amounts of target amplification (Column 37, lines 25-28 and 57-60). One of ordinary skill in the art would have been motivated to do so based on the economy of synthesis, hybridization, analysis and costs as taught by Skiena (Column 3, lines 45-48 and Column 4, lines 5-21).

Regarding Claim 2, Skiena teaches repeating the steps until the sequence is derived (Abstract).

Regarding Claim 3, Erlich teaches the target is a species variant of the reference sequence (Column 11, lines 28-59 and Abstract).

Regarding Claims 5-6, Erlich teaches the target shows 80-95% identity to the reference (Columns 17-18).

Regarding Claim 7, Erlich teaches the reference sequence is at least 1000 nt (i.e. DP alleles) and the probes are complementary to and span the reference sequence (Column 25, lines 1-29).

Regarding Claim 8, Skiena teaches the method wherein the estimated sequence includes an ambiguous nucleotide and the second probe set includes a probe aligned with the ambiguous nucleotide (Column 4, lines 11-22).

Regarding Claims 9-11, Erlich teaches the method wherein the reference sequence is a gene having allelic variants wherein the method is also useful for forensic and paternity testing (Abstract) but they are silent regarding a length of 10kb, 1000kb or 90% of the genome. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Erlich to sequence any length reference sequence e.g. 90% of the genome based on Erlich's suggestion of forensic and paternity testing (Abstract).

Regarding Claims 12-13, Erlich teaches the method wherein the probes comprise at least 4 probe sets wherein each probe in a set includes at least 6 nucleotides complementary to a subsequence of the reference wherein relative binding for the probes is determined to estimate the sequence of the target (Column 25, lines 1-57)

Regarding Claim 14, Erlich teaches the target differs from the reference by at least two positions (Columns 17-18).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erlich et al (U.S. Patent No. 5,310,893, issued 10 May 1994) in view of Skiena (U.S. Patent No. 5,683,881, issued 4 November 1997) as applied to Claim 1 above and further in view of Dietrich et al (U.S. Patent No. 5,861,243, filed 12 October 1990).

Regarding Claim 4, Erlich discloses a method for analyzing a target sequence comprising the steps of designing an array of probes that span a known sequence and immobilizing the probes (Column 12, lines 25-40), hybridizing the target to the immobilized probes, determining relative hybridization to estimate the sequence and using DPalpha/DPbeta hybridization-identification followed by variant-specific hybridization-identification (Column 11, lines 28-46). Erlich further teaches the method is useful in diagnostics (Abstract) but does not teach comparison of human reference sequence and primate target sequence.

However, comparison of human reference sequence and primate target sequence was well known in the art at the time the claimed invention was made as taught by Dietrich et al who teach that primates are a desired animal model for the study of HIV genotherapeutics (Column 3, lines 39-50). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the human reference sequence and primate target sequence taught by Dietrich et al to important DNA diagnostics taught by Erlich (Column 2, lines 5-12) based on the teaching of Dietrich et al wherein the primate is the desired animal model for the study of HIV genotherapeutics (Column 3, lines 39-50).

#### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42-47 of U.S. Patent No. 6,228,575. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of sequence analysis and differ only in the terminology used to describe the method steps. For example, the instant claims define the analysis using the terms "estimating" and "reestimating" while the '575 claims define the analysis using the terms "comparing" and "assigning". However, the terms refer to the same function i.e. sequence analysis. Therefore, the claims are not patentably distinct.

13. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/229,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to sequence analysis using very similar method steps and differ only in that the '319 methods are drawn to polymorphism analysis while the instant method are drawn to sequence variants. The '319 polymorphisms are a species of the instantly claims variants.

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed genus is obvious in view of the '319 species.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
June 21, 2005